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Dear Members of the Senate Banking and Insurance Committee,

This written testimony is in support of SB 1199, introduced by Senator Stewart Greenleaf. SB 1199 addresses many of the obstacles patients with Lyme disease face; this testimony will highlight several points about the bill.

Education is a critical component of any action which hopes to reduce the overall incidence of disease. Lyme disease continues to exhibit geographic expansion in Pennsylvania. According to the CDC, 97% of Pennsylvania's counties report at least one case of Lyme disease. Reported cases in 2009 were 113% higher than in 2008 and during 2009 Pennsylvania ranked first in the nation with 8,087 reported cases of Lyme disease. In fact, in 2009, 27% of all reported cases in the United States occurred in Pennsylvania.

To reduce the number of Lyme disease cases in Pennsylvania, educational efforts must be multi-faceted. The public needs to learn about Lyme disease, in general sense, so citizens will develop an increased awareness of the infection and it needs specific information regarding prevention strategies. There is also a need for people to learn the basics of diagnosing and treating Lyme disease so that they can be their own advocates and share in treatment decisions.

Physicians also need additional training with regards to Lyme and other tick-borne illnesses. I serve as the medical advisor to a Minnesota Lyme disease support group and know the difficulties patients encounter in trying to obtain a correct diagnosis. I also know that physicians are often confused as to how to treat patients, especially those with late disease. I'm sure you will receive testimony from Pennsylvanians whose doctors missed the diagnosis or were uncertain on how to treat. To combat this problem, I've written several courses on Lyme disease for various groups of health care professionals. My current course for primary care physicians was accredited for 6 prescribed credits by the American Academy of Family Physicians.

In researching and developing this course I've come to appreciate how much we have learned about this illness in the 30 years since its discovery. I also realize we have much yet to discover; there are many gaps in our knowledge. The lack of key elements in our scientific understanding of Lyme has led to differing opinions as to how the illness should be diagnosed and treated. Two major, and quite dissimilar, standards of care have evolved. Please see my editorial, which appeared in the Minneapolis Star Tribune on April 22, 2010, and my published peer-reviewed paper on the need for clinical judgment in Lyme disease; these were included in your packet of background material. Due to the controversy over testing, I am attaching a paper on serologic testing for Lyme disease which I wrote for attendees of my course.

SB 1199 may be considered a "physician protection bill" because it protects physicians from inappropriate medical board investigations and sanctions. These are important and necessary safeguards but SB 1199 is more than that because it's also about freedom. For patients, it's

freedom of choice. The AMA recognizes patient autonomy, meaning patients are free to choose their physician and course of treatment. Before they can act, patients must receive information about their options. This process is called informed consent and the AMA promotes it as a patient right. Informed consent requires physicians to discuss treatment options with patients, including the risks and benefits of each option. In Lyme disease, many physicians are quick to point out the potential risks and costs of antibiotics while minimizing their benefits. Yet, physicians rarely describe the risks and costs associated with not treating or under-treating and the benefits of short courses of antibiotics are often inflated. SB 1199 ensures that patients will receive balanced information and that their choices truly informed.

Unfortunately, without access to physicians who will honor their choices, patients lack true autonomy and informed consent. Some physicians in Pennsylvania are concerned the Board would use the IDSA guidelines to sanction physicians, making them reluctant to offer patients options. In this sense, SB 1199 also provides freedom to physicians who treat Lyme disease aggressively. The AMA's principles of medical ethics tell physicians that patient needs are primary and they should be an advocate for their patients; it's difficult to follow these principles when you believe doing so threatens your license and livelihood. By removing this perceived threat, SB 1199 frees physicians to use all of their skills when treating Lyme disease patients.

Many laws are created to strike a balance between the needs of the public and available resources; some laws are fashioned to encourage the growth of resources. Many Pennsylvanians with Lyme disease experience treatment delays because they can't find a physician who will honor their treatment choice. SB 1199 seeks to increase a scarce health care resource by removing obstacles that keep physicians from treating Lyme disease. In this sense, it is no different from other "resource growing" legislation.

Some claim that SB 1199 mandates a specific treatment approach for Lyme disease; this is simply untrue. SB 1199 does not dictate to patients what their care will be; rather, it grants them freedom to choose, within reason, the type of treatment which meets their needs. Likewise, physicians are not forced to treat in any particular manner but under SB 1199, and guided by their personal skill-set and experiences, they would be free to offer patients a variety of options. As the situation currently stands, the fear of sanctions is essentially mandating a single type of treatment, that which follows the restrictive recommendations of the IDSA guidelines.

Finally, let me discuss the issue of long-term antibiotic therapy; the safety of this approach is discussed in my paper on clinical judgment. Recommendations against the use of "long-term" antibiotics do not precisely define the term. While the rationale for limiting treatment duration is unclear, there are several clear reasons for treatment to be extended.

Borrelia burgdorferi invades protected sites and has the ability to inhabit intracellular locations.¹⁻
⁷ *B.burgdorferi* alters the immune response in multiple ways, favoring survival.⁸⁻¹² Because *B.burgdorferi* is able to avoid humoral, innate and cellular killing by the immune system, it results in patients being, for this particular pathogen, relatively immunocompromised. The survival strategies of *B.burgdorferi* are examples of "characteristics of other infections that justify longer treatment courses".

Long-term use of antibiotics may be one way to improve outcomes in certain subsets of patients. The treatment trials on early Lyme disease noted risk factors which were related to treatment failure. Dysesthesias,¹³ paresthesias,¹⁴ multiple EM,^{14,15} increased irritability,¹³ persistent fatigue,¹⁵ headache,¹⁵ stiff neck¹⁵ and increased severity of the initial illness¹⁵ were associated with an increased risk of treatment failure. Luft noted in his comparison trial of amoxicillin and azithromycin that the former performed better in human trials while the latter performed better in the test tube.¹⁶ He speculated that duration of therapy may be crucial. In an unrelated mouse study, Zeidner found that single-dose sustained-release doxycycline yielded measurable levels for 19 days and significantly out-performed a single oral dose in preventing Lyme disease post-tick bite.¹⁷ He, too, raised the theory that duration of therapy is important. Rather than offer shorter courses and wait for the expected failures, it would be reasonable to offer patients at high risk of failure alternative regimens utilizing a longer initial course of therapy.

Many patients in Pennsylvania struggle with late neurologic Lyme disease. To date, there have been only 4 studies that investigated treatment of this stage and these were uncontrolled trials involved a total of only 96 patients. The studies demonstrated treatment at this stage is difficult.^{18,19} In a 1990 study by Logigian et al., patients received IV ceftriaxone for 2 weeks.¹⁸ At 6 months post treatment, 63% were improved (not cured), 22 % had improved then relapsed and 15% were unchanged from baseline. These results suggest that 2 weeks of ceftriaxone therapy is inadequate. A follow-up study by the same author treated patients with Lyme encephalopathy with IV ceftriaxone for 30 days.¹⁹ At their final evaluation, only 39% considered themselves “normal”. One patient, who was improved at the 6 month follow-up visit, relapsed at 8 months and was retreated. Given these poor outcomes and the disability caused by neurologic Lyme disease, patients and physicians may decide that longer treatment durations are worth pursuing.

While some may argue that the re-treatment study by Klempner proved longer durations of antibiotic treatment are not useful,²⁰ that conclusion is faulty. A full discussion of that trial is beyond the scope of this testimony however, a critique of the study design used in the Klempner trial is applicable to this discussion. The study excluded patients who had received 60 or more days of IV antibiotics but patients who received less than 60 days remained eligible; 33% of the patients in the study had received IV antibiotics for a mean of 30 days. If prior experience can predict future outcomes, such patients would be more likely to fail than those who were never treated with IV antibiotics. Including them presents a selection bias favoring treatment failure (a curious design flaw for a treatment trial). Note that Logigian (1999) specifically excluded patients previously treated with 30 days of ceftriaxone from his trial and Dattwyler (2005) excluded patients who had previously been treated for late Lyme disease.^{19,21} Additionally, Klempner was a re-treatment trial and would not necessarily inform discussions on the use of long-term treatment as initial therapy for late neurologic disease.

Thus, the use of long-term antibiotic therapy is a reasonable approach to consider for patients with early Lyme disease at high risk for treatment failure, for patients with late Lyme disease and for those who have failed shorter courses of antibiotics for any stage of illness.

To summarize: SB 1199 seeks to reduce the burden of Lyme disease in Pennsylvania by educating the public and physicians on Lyme disease, emphasizing prevention. It acknowledges the limits of our scientific understanding of Lyme disease and the fact that two standards of care exist. It grants patients the freedom to choose their therapy and to act on those choices. It allows

physicians who offer an aggressive antibiotic approach to treatment the freedom to do this without fear of sanctions but it does not force them to treat in any particular fashion or at all. In short, SB 1199 serves the needs of Pennsylvania's citizens. Please support this legislation.

Most respectfully,

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